



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,729	11/17/2003	Jean-Pierre Sommadossi	06171.105062	5135
20786 7590 03/07/2007 KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309-3521			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		03/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/715,729	Applicant(s) SOMMADOSSI ET AL.	
	Examiner Louise Humphrey, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 33,34,37-52 and 87-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 33,34,37-52 and 87-108 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to Applicants' election filed on 20 January 2006 and supplemental election filed on 09 December 2006. Applicants elect Group IV. Upon further consideration, Group IV contains multiple inventions. In order for examination to further proceed expeditiously and with high quality, a restriction requirement is necessary as set forth below. The Office regrets any inconvenience this may cause Applicant.

Claims 1-32, 35, 36 and 53-86 have been cancelled. Claims 87-108 have been added. Claims 33, 34, 37-52 and 87-108 are pending.

In replacement of the previous restriction requirement is the following restriction:

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 33, 34, 37, 38, 48-52, and 87-108, drawn to a method for treating a Falviviridae infection in a host, comprising administering an effective amount of  $\beta$ -D-2'-CH<sub>3</sub>-riboC, classified in class 514, subclass 49.
- II. Claims 33, 34, 37, 39, 40, 48-52, and 87-108, drawn to a method for treating a Falviviridae infection in a host, comprising administering an effective amount of 3'-L-valinyl prodrug of  $\beta$ -D-2'-CH<sub>3</sub>-riboC, classified in class 560, subclass 19.
- III. Claims 33, 34, 41, 42, 48-52, and 87-108, drawn to a method for treating a Falviviridae infection in a host, comprising administering an effective amount of  $\beta$ -D-2'-CH<sub>3</sub>-riboA, classified in class 514, subclass 263.4.

Art Unit: 1648

- IV. Claims 33, 34, 41, 43, 44, 48-52, and 87-108, drawn to a method for treating a Falviviridae infection in a host, comprising administering an effective amount of 3'-L-valiniyl prodrug of  $\beta$ -D-2'-CH<sub>3</sub>-riboA, classified in class 514, subclass 263.1.
- V. Claims 33, 34, 41, 45, 48-52, and 87-108, drawn to a method for treating a Falviviridae infection in a host, comprising administering an effective amount of  $\beta$ -D-2'-CH<sub>3</sub>-ribo-6-N-methylaminopurine, classified in class 514, subclass 263.1.
- VI. Claims 33, 34, 41, 46-52, and 87-108, drawn to a method for treating a Falviviridae infection in a host, comprising administering an effective amount of 3'-L-valiniyl prodrug of  $\beta$ -D-2'-CH<sub>3</sub>-ribo-6-N-methylaminopurine, classified in class 514, subclass 263.1.

In addition, Applicants are required to select one formula from the numerous structural formulas set forth in claims 48-52 and 87-108 and one specific functional group formula for each of the following substituents: R', R1, R2, R3, R4 (claims 49 and 87-108), and base (claims 50-52).

For each of the base formula, Applicants are further required to select one formula for each of the following substituents:

If base formula is from the group of (i)-(vi), select one formula for each of G, L, D, E, W, R, Q6, Q5, Q7, Q11, and Q8;

If base formula is from the group of (A)-(E), select one formula for each of T1, T2, Q16, U, Y, R5, R6 m, Z, Q20, V1, and V2;

Art Unit: 1648

If base formula is from the group of (F)-(I), select one formula for each of T4, T3, Q22, T5, R5, R6, m, T6, T7, T8, T9, T10, T11, T12, U2, Y2, R, Q24, and Q26.

Applicants are further required to state the chemical name of the one selected compound that corresponds to its one structural formula.

There are multiple chemical compounds being claimed in the instant invention.

Claims 33, 34, 37-52 and 87-108 specifically claim multiple anti-Flaviviridae drugs, which are structurally distinct chemical compounds and are not related to one another. These compounds are deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. §121. Each such compound is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. §121 and 37 CFR 1.141 *et seq* (See MPEP §803.04).

Each sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. Substituents that are considered proper Markush members are, for example, fluorine, chlorine, bromine, and iodine. The instant claims contain functional groups such as cycloalkylamino, alkylsulfonyl, halogen, alkyl, peptide, carbohydrate, amino acid ester, which do not share a substantial core structure and have different chemical properties. Therefore, the substituents in each of claims 48-52

Art Unit: 1648

and 87-108 are not considered to constitute a proper genus/Markush, and are therefore subject to additional restriction.

Furthermore, a search of more than one (1) of the chemical compounds present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one (1) compound is considered to be a reasonable number for examination.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1648

**Correspondence**

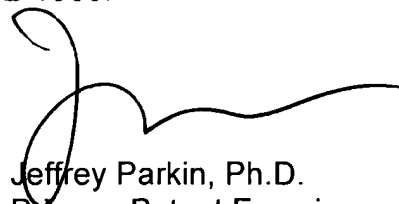
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Louise Humphrey, Ph.D.  
Assistant Patent Examiner  
28 February 2007



Jeffrey Parkin, Ph.D.  
Primary Patent Examiner